

### **REMARKS**

The present communication responds to the Office action dated January 10, 2008. In the Office Action, the Examiner rejected claims 1, 2, 4, 5 and 10 under 35 U.S.C. § 102(a)/(e), claims 1 and 3-6 under 35 U.S.C. § 102(b), and claim 7 under 35 U.S.C. § 103(a). In response thereto, claim 1 has been amended, claim 3 has been cancelled, and claims 24-25 have been added. In view of the amendments and the following remarks, Applicants request reconsideration and allowance of the pending claims.

#### **Claim Rejections under 35 U.S.C. § 102(b)**

##### **Claims 1, 2, 4, 5, and 10 are allowable over Jefferies**

Claims 1, 2, 4, 5 and 10 were rejected under 35 U.S.C. § 102(a)/(e) as being anticipated by US Pat. No. 6,311,690 (Jefferies). This rejection is traversed at least for the following reasons.

Claim 1, as amended, recites a method of making bone particles which comprises: a) at least partially immersing a quantity of bone in an immobilization medium; b) solidifying the immobilization medium to provide a solidified mass of bone and immobilization medium; c) subdividing the solidified mass of bone and immobilization medium to provide subdivided particles of bone and, d) separating the bone particles from the immobilization medium. Jefferies does not disclose the invention of claim 1 at least because it does not disclose “separating the bone particles from the immobilization medium.”

Jefferies discloses a material which is hemostatic and promotes the clotting of blood. *Jefferies*, col. 13, ll. 19-20. The material is produced by, first, adding an amount of demineralized bone powder (DBP) to a collagen mixture. *Jefferies*, col. 12, ll. 49-51. After processing, the DBP-collagen mixture is placed in petri dishes and frozen, under aseptic conditions, at minus 40°C. *Jefferies*, col. 13, ll. 9-10. The resultant foam-like material is placed in an A-10 mill and milled into a powder. *Jefferies*, col. 13, ll. 12-14.

Jefferies does not disclose separation of the DBP from the resultant powder. Moreover, it is unclear from the disclosure of Jefferies whether or not such separation is even possible. Additionally, as the resultant powder of Jefferies is a composition which exhibits desired

properties, namely, hemostatic properties, one having skill in the art would be discouraged from removing the DBP from the resultant powder. That is, removal of the resultant powder would likely vitiate the hemostatic properties of the resultant powder.

For at least these reasons, Jefferies does not disclose “separating the bone particles from their immobilization medium,” as recited in claim 1. Accordingly, Jefferies does not anticipate the invention of claim 1. Each of claims 2, 4, 5 and 10 depends from claim 1. The Applicants thus submit that Jefferies does not anticipate any of claims 2, 4, 5, or 10. Reconsideration and withdrawal of the rejection are respectfully requested.

*Independent Claim 1 and 3-6 are allowable over Kuberasampath*

Claims 1 and 3-6 were rejected under 35 U.S.C. § 102(b) as being anticipated by US Pat. No. 5,162,114 (Kuberasampath). This rejection is traversed at least for the following reasons.

Claim 1, as amended, recites a method of making bone particles which comprises: a) at least partially immersing a quantity of bone in an immobilization medium; b) solidifying the immobilization medium to provide a solidified mass of bone and immobilization medium; c) subdividing the solidified mass of bone and immobilization medium to provide subdivided particles of bone and, d) separating the bone particles from the immobilization medium. Kuberasampath does not disclose the invention of claim 1 at least because it does not disclose “solidifying the immobilization medium to provide a solidified mass of bone and immobilization medium.”

Kuberasampath discloses a preparation of demineralized bone. *Kuberasampath*, col. 7, ll. 31-33. Kuberasampath explains:

The bones are stripped of muscle and fat, cleaned of periosteum, demarrowed by pressure with cold water, dipped in cold absolute ethanol, and stored at -20° C. They are then dried and fragmented by crushing and pulverized in a large mill. *Kuberasampath*, col. 7, ll. 37-42.

After a defatting step, the pulverized bone is demineralized by four successive treatments of 0.5 N HCl. *Kuberasampath*, col. 7, ll. 44-52.

Kuberasampath does not disclose solidifying an immobilization medium. Rather, as described above, Kuberasampath discloses dipping a quantity of bone in absolute ethanol and storing the bone at -20° C. The Examiner is respectfully made aware of the fact that the freezing point of absolute ethanol is -114 ° C. *Sigma-Aldrich*, Ethanol 200 proof (Absolute). Accordingly, at -20° C any amount of absolute ethanol maintained in or on the bone after dipping would remain in the liquid phase. Thus, Kuberasampath does not disclose solidifying an immobilization medium.

For at least these reasons, Kuberasampath does not disclose “solidifying [an] immobilization medium to provide a solidified mass of bone and immobilization medium,” as recited in claim 1, as amended. Accordingly, Kuberasampath does not anticipate the invention of claim 1. Each of claims 3-6 depend from claim 1. The Applicants submit that Kuberasampath does not anticipate claims 3-6 at least for the reasons discussed with respect to claim 1. Reconsideration and withdrawal of the rejection are respectfully requested.

**Claim Rejections under 35 U.S.C. § 103(a)**

**Claim 7 is allowable over Stevenson**

Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over US Pat. No. 5,910,315 (Stevenson).

Claim 1, as amended, recites a method of making bone particles which comprises: a) at least partially immersing a quantity of bone in an immobilization medium; b) solidifying the immobilization medium to provide a solidified mass of bone and immobilization medium; c) subdividing the solidified mass of bone and immobilization medium to provide subdivided particles of bone and, d) separating the bone particles from its immobilization medium. Stevenson does not make obvious the invention of claim 1 at least because it does not disclose, teach, or suggest, “solidifying [an] immobilization medium to provide a solidified mass of bone and immobilization medium.”

Stevenson teaches an extrudable allograft bone tissue material for filling surgical sites. *Stevenson*, Abstract. To prepare the extrudable material, lyophilized bone tissue is placed in a syringe and reconstituted by adding a quantity of biocompatible fluid, such as sterile water.

*Stevenson*, col. 4, ll. 48-60. After the bone tissue has been sufficiently hydrated, it may be injected into a surgical site. *Stevenson*, col. 5, ll. 7-16. *Stevenson* does not teach or suggest solidification of the biocompatible fluid. Rather, as described above, *Stevenson* teaches hydration of lyophilized bone tissue by introduction of a sufficient quantity of biocompatible fluid prior. Indeed, subsequent solidification of the biocompatible fluid of *Steven* would frustrate the purpose of the invention; to provide an extrudable bone tissue material.

Accordingly, *Stevenson* does not disclose, teach, or suggest "solidifying [an] immobilization medium to provide a solidified mass of bone and immobilization medium," as recited in claim 1. Claim 7 depends directly from claim 1. Accordingly, this claim is also patentable for at least for the reasons presented above and, further, in view of its additional recitations. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion


This application now stands in allowable form and reconsideration and allowance are respectfully requested.

This response is being submitted on or before April 10, 2008, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

DORSEY & WHITNEY LLP  
Customer Number 25763

Date: 4/10/08

By:   
Kenneth E. Levitt, Reg. No. 39,747  
(612) 340-2755